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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Paper No. 16

Application Number: 09/834,440

Filing Date: April 13, 2001

Appellant(s): KHALIL ET AL.

David L. Weinstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 7/25/2003.

(1) *Real Party in Interest*

A statement identifying the real party in interest is contained in the brief.

(2) *Related Appeals and Interferences*

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) *Status of Claims*

The statement of the status of the claims contained in the brief is correct.

(4) *Status of Amendments After Final*

The appellant's statement of the status of amendments after final rejection contained in the brief is incorrect.

The amendment after final rejection filed on 7/25/2003 has been entered.

(5) *Summary of Invention*

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows: claims 9-18 have been amended in Amendment filed on 9/3/2002 which traverses the rejections under 25 U.S.C. 112, second paragraph. Only Issues #2 and #3 remain.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because the Applicant has provided the same arguments for both groups of claims. A decision made for one grouping would automatically parallel the decision for the other grouping.

(8) ClaimsAppealed

A substantially correct copy of appealed claims 1-18 appears on pages 11-15 of the Appendix to the appellant's brief. The minor errors are as follows: claims 9 and 17 have been amended in response to the amendment that was filed with the Applicant's Brief on 7/25/2003. In particular, --of a human subject—was inserted after part in claim 9, line 2 and “[collecting]” was deleted in claim 17, line 7.

(9) Prior Art of Record

5,978,691 A	Mills	11-1999
5,800,347 A	Skates et al.	09-1998

(10) *Grounds of Rejection*

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-4, 6-7, 9-12, 14, and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent 5,978,691 to Mills. Mills teaches a device for noninvasively determining oxygen saturation, partial pressure of oxygen, partial pressure of carbon dioxide, concentration of bicarbonate ion and total carbon dioxide, acid-base balance, base excess, hemoglobin level, hematocrit, oxyhemoglobin level, deoxyhemoglobin level, and oxygen content. (Abstract of Mills). Mills teaches the two probes at different locations at two different temperatures are used to calculate oxygen saturation. (column 12, lines 6-42 of Mills). Mills teaches a mathematical relationship (column 9, line 56 to column 11, line 56 of Mills). In regard to claims 1 and 7, the device can be used to detect cancers. (column 14, lines 20-25 of Mills). In regard to claims 2 and 10, 660nm and 940 nm can be used. (Fig. 11 of Mills). In regard to claims 3 and 11, reflectance can be employed, (column 8, lines 1-3 of Mills). In regard to claims 4 and 12, simultaneous measurements can be taken. (column 12, lines 6-22 of Mills). In regard to claims 6 and 14, temperatures ranging from 33-40 °C can be used. (column 12, lines 6-42 of Mills). In regard to claims 9 and 16, the device can be used to determine glucose. (column 13, lines 28-42 of Mills).

Claims 5, 13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills (cited by Applicant) as applied to claims 1 and 9. In regard to claims 5 and 13, Mills does not teach an embodiment in which the two probe locations are taking measurements at different temperatures in a sequential fashion. Mills teaches two probe locations in which measurements are taken at different temperatures simultaneously. (column 12, lines 6-13 of Mills). Mills also teaches a single probe location in which measurements are taken at different temperatures in a sequential fashion. (column 11, lines 59-67 of Mills). Mills is implying that his method does not require that the both measurements at different temperatures are taken simultaneously since one method allows for sequential measurements. This implication would lead to one with ordinary skill in the art to believe that sequential measurements are a valid option if desired due to design considerations. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device with multiple measurement locations to include sequential measurement taking since Mills implies that such a method is valid. In regard to claim 15, Mills does not explicitly teach providing a population comprising a sufficient number of subjects to establish a category selector or to establish a statistically meaningful relationship. Mills teaches the use of normal volunteers during calibrating mathematical relations. (column 9, lines 44-53 of Mills). It is known in the art that calibration using human subjects are performed when determining a computation model for an optical diagnostic device. It is also well known in the art that the required accuracy of the model and the availability of subjects are factors to determining when determining

calibration procedures. This information provides a clear suggestion that the number of subjects can be modified and that the determination of the most appropriate number of subjects by routine experimentation would, therefore, be *prima facie* obvious to one having ordinary skill in the art.

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent 5,978,691 to Mills (cited by Applicant) as applied to claim 1 in view of U.S. Patent 5,800,347 to Skates et al. Mills does not explicitly teach of providing a population comprising a sufficient number of subjects to establish a category selector in which the number of subjects comprises a sub-population of humans in a disease state and a sub-population of humans not in a disease state. Mills teaches the use of normal volunteers during calibrating mathematical relations. (column 9, lines 44-53 of Mills). Mills implies that such calibration using human subjects is used when determining a computation model for an optical diagnostic device. It is also well known in the art that the required accuracy of the model and the availability of subjects are factors to determining when determining calibration procedures. One method of establishing mathematical relations from calibration is using a statistical analysis of measurements on normal and diseased populations to establish multivariate algorithms. (Abstract of Skates et al.). Such multivariate algorithms are used to establish measurement thresholds to aid in diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold. (column 4, lines 16-53 of Skates et al.). Therefore, it would have been obvious to one having

ordinary skill in the art at the time the invention was made to use the calibration method as disclosed by Skates et al. in the method and apparatus of Mills since multivariate algorithms are used to establish measurement thresholds to aid in diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold.

(11) Response to Argument

Issue 1

This issue is moot since claims 9-18 have been amended in the Amendment filed on 9/3/2002 which traverses the rejections under 25 U.S.C. 112, second paragraph.

Issue 2

The Applicant contends that Mills does not teach at least one optical property is measured at a first area on a body part of a human subject using a first temperature program and another optical measurement on a second area of the body part which is morphologically similar, adjacent, but not substantially overlapping with a second temperature program. The Examiner respectfully disagrees. The Examiner interprets the language of the claims more broadly than the Applicant. Figs. 5b and 5c clearly show that the optical measurements are taken on a body part, i.e. the hand. Nothing in the specification or claims limits the definition of a "body part" from its plain and ordinary meaning of any portion of person's anatomical structure and the hand falls within that meaning. Figs. 5b and 5c also show that the optical measurements are taken on

adjacent areas that are morphologically similar, i.e., adjacent fingers. Nothing in the specification or claims limits the definition of "adjacent" from its plain and ordinary meaning of "close to" or "next to". Using this interpretation of the meaning of the claim terms, Mills anticipates the invention disclosed in the present application.

The Applicant provides three statements that allegedly distinguish the method and apparatus of Mills from the method and apparatus of the present invention. The first statement is unpersuasive since Mills does not use the term "body part" or "adjacent" to describe the placement of the apparatus. Mills merely describes locations in which the measurements can be taken and is not attempting to define the term "body part". The second statement pointed out by the Applicant is equally unpersuasive. The Applicant's claims do not include any limitation that would limit the Applicant's claimed device in such a way that the device cannot be used in trans-illumination measurements. The Applicant contends that the limitation that the first and second areas of the body are "morphologically similar" is such a limitation but the contention is not persuasive since the fingers, as seen in Figs. 5b-c of Mills, are similar in shape and structure, thereby making them "morphologically similar" as defined by the plain and ordinary meaning of the term. Even if the Applicant included a limitation in the claims that would limit the Applicant's claimed device so that it would not be used in transillumination measurements, Mills teaches that the method and apparatus works in reflectance measurements as noted by the second statement indicated by Applicant. The use of the method and apparatus of Mills in reflectance measurements would read on any such limitation. The third statement indicated by the Applicant is also not

relevant to the determination of what is meant by a “body part” since the passage does not even address the embodiment that the Examiner is relying on for the rejections. In view of these observations, the three statements of Mills that are relied upon by the Applicant are not persuasive and the invention of Mills is not distinguished from the invention of the present application.

In view of the preceding arguments, Mills discloses the claimed invention of the present application.

Issue 3

The Applicant first contends that Mills does not disclose or suggest the division of the population of human subjects into two subpopulations, as stated in claim 8. The Examiner agrees that Mills does not explicitly teach this limitation. The Applicant, however, does not contend that the combination of Mills and Skates et al. does not teach the division of the population of human subjects into two subpopulations. Although Mills does not disclose the division into two subpopulations, Mills teaches the use of normal volunteers during calibrating mathematical relations. (column 9, lines 44-53 of Mills). Mills acknowledges that it is well known in the art to use human subjects when determining a computation model for an optical diagnostic device. Skates et al. teaches a method of establishing mathematical relations from calibration using a statistical analysis of measurements on normal and diseased populations to establish multivariate algorithms. (Abstract of Skates et al.). Skates et al. further teaches that such multivariate algorithms are used to establish measurement thresholds to aid in

diagnosing the patient by identifying a diseased state above (or below) a certain threshold and a healthy state below (or above) that threshold. (column 4, lines 16-53 of Skates et al.). Indeed, the whole purpose of taking medical measurements, in general, is for the determination of the presence or absence of diseased states to better treat a patient. Skates et al. provides the teaching, which is lacking in Mills, of the division of the population of into two subpopulations, those with disease and those who are healthy, when equating a computation model to human subjects. As such, the combination of Mills and Skates et al. meets all the limitations of claim 8 of the present application.

The Applicant then repeats the same arguments, as provided in issue 2, that Mills does not teach at least one optical property is measured at a first area on a body part of a human subject using a first temperature program and another optical measurement on a second area of the body part which is morphologically similar, adjacent, but not substantially overlapping with a second temperature program. The Examiner again respectfully disagrees. The Examiner interprets the language of the claims more broadly than the Applicant. Figs. 5b and 5c clearly show that the optical measurements are taken on a body part, i.e. the hand. Nothing in the specification or claims limits the definition of a "body part" from its plain and ordinary meaning of any portion of person's anatomical structure and the hand falls within that meaning. Figs. 5b and 5c also show that the optical measurements are taken on adjacent areas that are morphologically similar, i.e., adjacent fingers. Nothing in the specification or claims limits the definition of "adjacent" from its plain and ordinary meaning of "close to" or

"next to". Using this interpretation of the meaning of the claim terms, Mills discloses the invention disclosed in the present application.

The Applicant reasserts three statements of Mills that allegedly distinguish the method and apparatus of Mills from the method and apparatus of the present invention. The first statement is unpersuasive since Mills does not use the term "body part" or "adjacent" to describe the placement of the apparatus. The second statement is equally unpersuasive since the Applicant's claims do not include any limitation that would limit the Applicant's claimed device in such a way that the device cannot be used in trans-illumination measurements. Even if the Applicant included a limitation in the claims that would limit the Applicant's claimed device so that it would not be used in transillumination measurements, Mills teaches that the method and apparatus works in reflectance measurements, which would read on such claims. The third statement is also not relevant to the determination of what is meant by a "body part" since the passage does not even address the embodiment that the Examiner is relying on for the rejections. In view of these observations, the three statements of Mills that are relied upon by the Applicant are not persuasive and the teachings of Mills are not distinguished from the teachings of the present application.

In view of the preceding arguments, the claimed invention of the present application is obvious in view of Mills for claims 5, 13, and 15 and obvious in view of Mills and Skates et al. for claim 8.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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September 17, 2003

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